

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



23 APR 2005

(43) International Publication Date
6 May 2004 (06.05.2004)

PCT

(10) International Publication Number
WO 2004/037175 A3

- (51) International Patent Classification⁷: **C12Q 1/68** (74) Agent: BRENNAN, Jack; Fish & Richardson P.C., Suite 2800, 45 Rockefeller Plaza, New York, NY 10111 (US).
- (21) International Application Number: PCT/US2003/032705 (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (22) International Filing Date: 16 October 2003 (16.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/420,068 21 October 2002 (21.10.2002) US
60/471,481 15 May 2003 (15.05.2003) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:
US 60/471,481 (CON)
Filed on 15 May 2003 (15.05.2003)
US 60/420,068 (CON)
Filed on 21 October 2002 (21.10.2002)
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- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 29 July 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*



WO 2004/037175 A3

(54) Title: COMPOSITIONS AND METHODS FOR TREATING HUMAN PAPILLOMAVIRUS-MEDIATED DISEASE

(57) Abstract: The invention includes methods of treating an HPV-mediated disease by administration to an individual of a pharmaceutical composition comprising a nucleic acid that encodes a polypeptide comprising an epitope of a naturally occurring HPV protein. The methods include the selection of individuals for treatment with the composition according to the age of the recipient, as well as the use of the composition to elicit a cross-reactive anti-HPV immune response.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/32705

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68

US CL : 435/6

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,306,397 B1 (EDWARDS et al) 23 October 2001 (23.10.2001), see the claims.	1, 2, 9-13
Y	KLENCKE et al. Encapsulated Plasmid DNA Treatment for Human Papillomavirus 16-associated Anal Dysplasia: A Phase I Study of ZYC101. Clinical Cancer Reseach. May 2002, Vol. 8, pages 1028-1037, see the abstract.	1, 2, 9-13
Y	MOSCICKI A.B. Human Papillomavirus Infection In Adolescents. Pediatric Clinics of North America. August 1999, Vol. 46, No. 4, pages 783-807, see page 793.	1, 2, 9-13
Y	HEDLEY et al. Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nature Medicine. March 1998, Vol. 4, No. 3, pages 365-368, see the entire document.	1, 2, 9-13



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

14 April 2004 (14.04.2004)

Date of mailing of the international search report

27 MAY 2004

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/32705

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claim Nos.: 16-50
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1, 2, 9-13

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Edwards et al (US Patent NO. 6,306,397 B1, October, 23, 2001) wherein the reference teaches a method of treating HPV is host (see claims 1, 2, 21, 32, and column 5, lines 58-65). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1, 2, 9-13, drawn to method of treating cervical intraepithelial neoplasia. (1st method)

Group II, claim(s) 3, 4, 9-15, drawn to method of treating human papillomavirus mediated disease. (2nd method)

Group III, claim(s) 5, 6, 9-13, drawn to method of selecting a treatment for an individual. (3rd method)

Group IV, claim(s) 7-13, drawn to kits. (1st product)

Group V, claim(s) 51, 52, 69-72, drawn to method of treating CIN. (4th method)

Group VI, claim(s) 53, drawn to method of treating CIN. (5th method)

Group VII, claim(s) 54, drawn to method of treating CIN. (6th method)

Group VIII, claim(s) 55, drawn to method of treating CIN. (7th method)

Group IX, claim(s) 56, drawn to method of treating HPV. (8th method)

Group X, claim(s) 57, drawn to method of treating HPV. (9th method)

Group XI, claim(s) 58, drawn to method of treating HPV. (10th method)

Group XII, claim(s) 59, drawn to method of treating HPV. (11th method)

Group XIII, claim(s) 60, drawn to method of treating HPV. (12th method)

Group XIV, claim(s) 61, drawn to method of selecting treatment (13th method).

Group XV, claim(s) 62, drawn to method of selecting treatment (14th method).

Group XVI, claim(s) 63, drawn to Kit. (2nd product)

Group XVII, claim(s) 64, drawn to Kit. (3rd product)

Group XVIII, claim(s) 65, drawn to Kit. (4th product)

Group XIX, claim(s) 66, drawn to Kit. (5th product)

Group XX, claim(s) 67, drawn to Kit. (6th product)

INTERNATIONAL SEARCH REPORT

PCT/US03/32

Group XXI, claim(s) 68, drawn to Kit. (7th product)

Continuation of B. FIELDS SEARCHED Item 3:

MEDLINE, DERWENT, EPA, JAP, CAPLUS, NPL, WEST

Search terms: Papillomavirus, cervical intraepithelial neoplasia, CIN, treatm?, adolescent, young age